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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,233

08/27/2003

Mark Gelfand

3659-72

3768

23117 7590 01/12/2007
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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/648,233

Applicant(s)

GELFAND ET AL.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13 and 22-31 is/are rejected.
- 7) ☒ Claim(s) 9-12 and 14-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/27/03; 4/22/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-16, 22-28, and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13, 15, 16, and 18-25 of U.S. Patent No. 6,689,083 to Gelfand et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly presented claims comprise all of the steps of the method listed in the '083 patent, resulting in a broader recitation of the method already patented by applicant.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8, 13, and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,202,764 to Afflerbaugh et al in view of US 3,926,797 to Gigou et al.

In the specification and figures, Afflerbaugh discloses the method substantially as claimed by applicant. With regard to claims 1, 13, and 22, Afflerbaugh discloses an ultrafiltration control system and method that prevents an undesirable side effect upon removal of too much water from a patient, which can result in hypotension (see column

Art Unit: 3761

1, lines 53-63). The method includes the step of withdrawing blood from a patient in circuit through withdrawal and infusion lines 12a,b, treating it with a dialyzer 12, and returning blood to the patient (see column 2, line 50 to column 3, line 35). The method further includes the step of monitoring the pressure within the system and using a pump to adjust the flow of fluids through the treatment system to reach a desired pressure measurement (see column 2, lines 19-50).

Afflerbaugh fails to disclose that the pressure monitored within the system is an osmotic pressure. However, Gigou discloses a blood purification process that monitors and adjusts osmotic pressure within the system to control micturition (see column 4, lines 8-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to incorporate the control of osmotic pressure as disclosed by Gigou into the ultrafiltration control method disclosed by Afflerbaugh, in order to control micturition, as taught by Gigou.

With regard to claims 2-5, Gigou discloses that the osmotic pressure is a result-effective variable that may be controlled by various system adjustments (see column 4, lines 8-23). As such, the use of a particular osmotic pressure for the control of the system is within the scope of the Gigou disclosure, which adjusts osmotic pressure between a desired minimum and maximum level. It has been held that where the general conditions of a claim are found in the prior art it is an obvious variation of the art to find the optimum or workable ranges through routine experimentation. See MPEP 2144.05(II)(A). It is the position of the examiner that Gigou discloses the general conditions of controlling osmotic pressure during a blood filtration procedure, and setting

the parameters by which the osmotic pressure is controlled is a result of routine experimentation. Therefore, applicant's claims drawn to the control of the osmotic pressure by specific parameters are an obvious variation of the procedure disclosed by Afflerbaugh and Gigou.

With regard to claim 6, Gigou discloses that the osmotic pressure adjustments may be made by human control, meeting the limitations of the claim.

With regard to claims 7 and 8, Afflerbaugh discloses that pressure measurements are taken across the membrane of dialyzer 12 within the blood circuit (see column 5, lines 16-23).

With regard to claim 23, Afflerbaugh discloses that the filtration device comprises a controller 52 that stores algorithms to control the operation of the system based on predetermined and measured parameters (see column 5, lines 1-15).

With regard to claims 24 and 25, such a statement of the operation of the device is considered by the examiner to be a statement of the intended use of the claimed device. It has been held that recitations with respect to the manner in which a claimed apparatus is intended to be employed fail to differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the controller disclosed by Afflerbaugh is capable of being programmed to operate as claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 26-28, Afflerbaugh discloses that dialyzer 12 filters blood and performs ultrafiltration, rendering it a hemofilter and dialyzer, as well as an ultrafilter (see column 2, lines 19-50).

With regard to claim 29, Gigou does not disclose an actual osmotic pressure sensor, but does disclose that the osmotic pressure of various fluids in the system may be controlled by the system, suggesting the presence of an osmotic pressure sensor, necessary to control the osmotic pressure, that may be located within the treatment system.

With regard to claims 30 and 31, Afflerbaugh discloses pressure sensors 44, 46, 48, 50 located in the blood lines and the filtrate lines that together measure the difference between blood pressure and filtrate pressure during system operation (see column 5, lines 16-23).

Allowable Subject Matter

5. Claims 9-12 and 14-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the method claimed by applicant. In particular, the prior art fails to suggest a method of preventing hypotension in a patient as presented in the independent claims in combination with the step of periodically stopping and restarting fluid flow through the system to measure the osmotic pressure within the filtration system, along with the other steps and limitations of the claims.

Conclusion

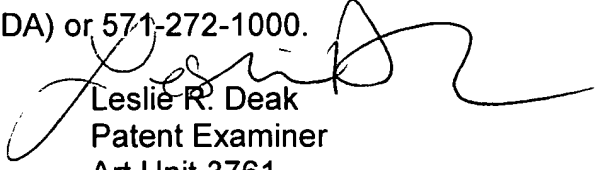
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 4,680,122 Barone
 - i. Ultrafiltration control by monitoring and adjusting pressure

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
5 January 2007